



Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax : 613-761-4311
<http://www.ohri.ca/ohreb>

**APPLICATION FOR RETROSPECTIVE CHART REVIEW
OF PATIENT RECORDS**

PROTOCOL NUMBER:	
PROTOCOL TITLE:	
CAMPUS	<input type="checkbox"/> CIVIC <input type="checkbox"/> GENERAL <input type="checkbox"/> RIVERSIDE <input type="checkbox"/> OTHER:

PRIMARY INVESTIGATOR FOR MULTICENTRE TRIALS

Last Name		First Name	
Title/Position		Department & Location	
Tel.	() - ext.	Fax	() -
Email			

PRINCIPAL INVESTIGATOR AT THE OTTAWA HOSPITAL

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -
Dept/Unit & Location		Email	
Division/Portfolio		Signature:	

CO-INVESTIGATORS

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -
Dept/Unit & Location		Email	
Division/Portfolio		Signature:	

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -

Dept/Unit & Location		Email	
Division/Portfolio		Signature:	

APPROVAL BY INVESTIGATOR'S DEPARTMENT OR DIVISION HEAD

Hospital and university division and department administrators are responsible for academic activities within their unit, and may provide guidance and support to investigators. The purpose of this signature section is to ensure that administrators are aware of research activities and the impact of these activities.

- The study answers a reasonable scientific/clinical question and is consistent with hospital/faculty policies and mission.
- The study resources (budget, space, support staff) are adequate to support the study.
- The local investigators are qualified to perform the study.
- There are an adequate number of research participants suitable to be approached for enrolment for this study. This population is not already over-subscribed in clinical research.

I have reviewed this application and agree it should be submitted for ethics approval.

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -
Dept/Unit & Location		Email	
Division/Portfolio		Signature:	

Contact Person (where appropriate)

Last Name		First Name	
Title/Position		Tel.	() - ext.
		Fax	() -
Dept/Unit		Email	
Division/Portfolio		Signature:	

Type of Study

Which of the following best describes the type of investigation proposed? Check more than one if appropriate.

Describe the Research Project by checking as many of the following as apply:	
Study Type:	
<input type="checkbox"/>	Experimental Research/Clinical Trial
<input type="checkbox"/>	Observational Research
<input type="checkbox"/>	Pilot
<input type="checkbox"/>	Sequel to previously approved project (Protocol #)
<input type="checkbox"/>	Retrospective Chart Review
<input type="checkbox"/>	Program Evaluation
<input type="checkbox"/>	Medical Device Research

<input type="checkbox"/> Single Centre Trial	<input type="checkbox"/> Multicentre Trial
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Study Design:	
<input type="checkbox"/> Randomized, controlled trial	
<input type="checkbox"/> Phase I	<input type="checkbox"/> Phase II
<input type="checkbox"/> Phase III	<input type="checkbox"/> Phase IV
<input type="checkbox"/> Single Blinded	<input type="checkbox"/> Double Blinded (or more)
<input type="checkbox"/> Case-Control study	
<input type="checkbox"/> Cohort study	
<input type="checkbox"/> Interview, survey or questionnaire, observation	
<input type="checkbox"/> Quality Assurance	
<input type="checkbox"/> Evaluation of Medical Devices	
<input type="checkbox"/> Compassionate Use	
<input type="checkbox"/> For Publication	
<input type="checkbox"/> Evaluation Research	
<input type="checkbox"/> Other (specify:)	

STUDY DURATION	Start Date: <u> / / </u> DD/MM/YYYY	End Date: <u> / / </u> DD/MM/YYYY
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FUNDING SOURCE (If there is no funding, indicate 'Not Applicable')

	Name	Amount
Granting Agency		
Hospital		
Hospital Foundation		
Departmental Research Funds		
Drug Company/Industrial		
Other		
Not Applicable		

SUMMARY OF RESEARCH PROPOSAL

Purpose and Rationale:

Chart Review Plan

Sample Size		Will there be patient contact?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Patient Population			

Conditions, demography, source, time period for retrospective chart review (i.e. 2006-2007)

If list of cases for chart review required please specify ICD codes that best describe patient population:

Confidentiality

Will an electronic database be created? Yes No

(The following information **must be included** in this section to avoid delays in processing the application):

- ثفا Confirm that an independent study number will be assigned to each patient record.
- ثفا What information will be collected? (A 'Case Report Form' may be provided with these details). No identifying information should be used such as hospital unique numbers, OHIP#, etc. – if any identifying information is required, justification must be provided.
- ثفا Date of birth is considered a personal identifier. Confirm that you are not using date of birth. If it is required, clarify whether month and year of birth will suffice? If you require full date of birth, justification must be provided.
- ثفا Indicate how the master list linking the patient to the independent study number will be maintained and safeguarded, and confirm that it will be stored separately and securely.
- ثفا Indicate how data containing Personal Health Information (PHI) will be protected against breaches of privacy. (i.e. locked cabinets? password protected?)
- ثفا Indicate which organizations and/or individuals will have access to PHI. Add the OHREB and OHRI.
- ثفا Confirm that no PHI will be leaving the Ottawa Hospital.
- ثفا Confirm that all study records will be kept for a period of **15 years.**
- ثفا Indicate how paper and electronic data will be destroyed once the storage date has expired (shredded? deleted?)

THE OTTAWA HOSPITAL RESEARCH ETHICS BOARD POLICY PROHIBITS THE RELEASE OF ANY IDENTIFYING INFORMATION FROM THE HOSPITAL.

STATEMENT OF UNDERSTANDING

Reviews will be conducted by members of the Ottawa Hospital Medical/Dental Staff, House Staff or Research assistants working for the Medical staff. Projects to be conducted by external groups will be sponsored by the Chief of the Clinical Department/Division under review. If patient contact is required for the study, this must be stated in the application. If the review is being conducted in preparation for publication, the permission of the attending physician must be secured.

Due to space limitations and the need for chart control, records can only be out of file for 2 weeks. If review has not begun by this time the principal investigator will be contacted and the charts returned.

Confidentiality:

The hospital records which you will be reviewing contains information which patients have the right to expect will be held in confidence. Please review the following items concerning confidentiality and research and sign the Statement of Understanding.

1. Patient’s records retrieved for review will be stored and used in the Health Records department where access can be controlled.
2. Health data, which is abstracted for research or educational purposes, must be collected in an unidentifiable format. A unique identifier, un-linkable with any other non-health data system is recommended.
3. All working papers generated by the review will be stored in a secure area and will be shredded when they are no longer useful.
4. OACIS access will be in accordance with TOH policies.

Statement of Understanding:

- I have read the policy on Confidentiality and the Research Guidelines.
- I understand that all health information which I may access is confidential and is to be dealt with
in keeping with TOH policies on Confidentiality, Privacy and Security.

Principal Investigator:

_____	_____
<i>(Print name)</i>	<i>(Signature)</i>

Research Assistant(s):

_____	_____
<i>(Print name)</i>	<i>(Signature)</i>

_____	_____
<i>(Print name)</i>	<i>(Signature)</i>

_____	_____
<i>(Print name)</i>	<i>(Signature)</i>

_____	_____
<i>(Print name)</i>	<i>(Signature)</i>

(Print name)

(Signature)

Attachment B

HEALTH DATA & INFORMATION SERVICE FEE STRUCTURE

Please complete the following impact analysis to determine chart review resource requirement.

Description Of Work:	Cost per Unit/Hour	Service Used	Total Cost
Analyst Consultant Fee:			
Report Writing	\$50.00		
Data Retrieval from Microfiche / CIHI Reports	\$50.00		
Extraction of Data from Patient Records	\$50.00		
Compilation and Presentation of Data	\$50.00		
Clerical Service fee:			
Central Patient Index Searches	\$25.00		
Chart Retrieval:			
On Site	\$1.00		
Off Site:	\$2.50		
Microfilm, Microfiche Retrieval	\$2.50		
ICES	\$4.00		
Cancer Care Ontar	\$2.00		
Photocopying/Printout:			
Record	\$0.35		
Oacis	\$0.35		
Scanned Record	\$0.35		
Minimum Fee	\$25.00		
Other	TBD		
Total Health Records Services:			

Billing Address:

Principal Investigator:

(Print name)

(Signature)

Approved by Health Data & Information Service:

Rina Marcantonio
Civic Campus

(Signature)

Date

Sylvie Demers
Christine Leclair
General Campus

(Signature)

Date

Sheila Lessard
Riverside Campus

(Signature)

Date

CHART REVIEW PROCESS

- **Research Applicant**
 - Complete Application for Research Ethics Approval, including Attachment A (Statement of Understanding), B (HDIS Fee Structure) and Departmental Impact Form (all forms can be found on OHREB website)
 - Meet with Clinical Information Analyst (CIA) in Health Records
 - Submit copy of completed Application to CIA
- **CIA**
 - Review Application for completeness
- **Research Applicant and CIA**
 - Meet to discuss study criteria
 - Review and sign Attachment B
- **OHREB**
 - Receive completed and signed Application
 - Review and assign Protocol number, if acceptable
 - Complete Approval for Review of Patient Records and forward to applicant
- **Research Applicant**
 - Present Approval Letter and Protocol number to CIA
- **Research Applicant, CIA and Clerical Staff**
 - Review Research and Chart Review Guidelines
 - Arrange to have charts pulled (Campus-specific policies and procedures are in effect)
- **Research Applicant**
 - Notify CIA of any amendment(s), renewal or termination of study

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